K073214

510(k) Summary for Duowedge

DEC - 1 2009

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for Duowedge.

Date Prepared: February 13, 2009

1. **Submitter:**
Kasios
Z.I. La Croix - 8, impasse de la Feuilleraie
31140 Launaguet
France

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** Duowedge Bone Substitute
Common Name: bone substitute
Classification Name: Resorbable Calcium Salt Bone Void Filler
Per CFR section 888.3045
Class II
MQV

3. **Predicate or legally marketed devices which are substantially equivalent:**
Duowedge is substantially equivalent to similar previously cleared bone substitutes

4. **Description of the device:**
The calcium phosphate ceramic Duowedge manufactured by KASIOS is designed to be used as a bone void filler tibial osteotomies. Duowedge is a synthetic bone substitute. It is a macroporous bioceramic, made of hydroxyapatite and beta tricalcium phosphate. When packed into a bony site, Duowedge gradually and partially resorbs and is replaced with bone during the healing process. In addition, Duowedge is intended to be used with appropriate opening osteotomy system devices, plates and screws. Duowedge is for use in combination with adequate post-operative immobilization.

Materials:
Biphasic porous ceramic composed of hydroxyapatite Ca10(PO4)6(OH)2 and tricalcium phosphate Ca3(PO4)2. These calcium phosphates are manufactured and controlled by Kasios in compliance with ASTM F 1185 and ASTM F 1088 standards

5. **Intended Use:**
When used with appropriate opening osteotomy system devices, plates and screws, Duowedge is intended to be used as a bone void filler in tibial osteotomies. Duowedge is to be used in combination with adequate post-operative immobilization.

6. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**
Duowedge has the same indications and material, and similar designs as previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC - 1 2009

Kasios
% The OrthoMedix Group, Inc.
J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K073214
Trade/Device Name: Duowedge Synthetic Bone Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: September 8, 2009
Received: September 9, 2009

Dear J.D. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073214

Device Name: Duowedge

Indications for Use:

When used with appropriate opening osteotomy system devices, plates and screws, Duowedge is intended to be used as a bone void filler in tibial osteotomies. Duowedge is to be used in combination with adequate post-operative immobilization.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K073214